UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *The Montgomery County Board of County Commissioners et al. v. Cardinal Health, Inc., et al.*, Case No. 1:18-op-46326-DAP	MDL 2804 Case No. 1:17-md-2804 Judge Dan Aaron Polster

PLAINTIFF'S REPLY MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF PATRICK J. MARSHALEK

Plaintiff seeks to exclude two specific categories of the opinions of Defendant Kroger's expert, Dr. Patrick J. Marshalek, because Dr. Marshalek does not have the knowledge or experience to opine about pharmacy practice or federal regulation. In response, Kroger merely asserts that Dr. Marshalek's experience in other areas, including clinical practice and consulting, provides the requisite expertise, but it fails to demonstrate how this is so. Indeed, Dr. Marshalek's deposition testimony not only fails to demonstrate any meaningful knowledge about the topics Plaintiff seeks to exclude, which is particularly on display in his ignorance of the concepts of corresponding responsibility, due diligence, and red flags, but also fails to establish that his experience in other areas is a sufficient basis to support his opinions on the two categories of information at issue here. The Court should grant Plaintiff's motion to exclude Dr. Marshalek's opinions about pharmacy practice and about federal regulation.

ARGUMENT

"An expert may be highly qualified to respond to certain questions and to offer certain opinions, but insufficiently qualified to respond to other, related questions or to opine about other areas of knowledge." *In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2021 WL 4243084, at *7 (N.D. Ohio Sept. 17, 2021) (quotation marks and citation omitted). Such is the case here. Kroger argues that

Dr. Marshalek possesses the knowledge and experience to opine about pharmacy practice and federal regulation of the opioid industry, relying primarily on Dr. Marshalek's "extensive experience as a healthcare provider, healthcare administrator, and DEA consultant" as the basis for these opinions. Opp'n at 1. Plaintiff has already described in detail Dr. Marshalek's evident lack of knowledge in these areas. *See* Pl.'s Mem. (Dkt. 4885) at 4–7 (lack of knowledge about pharmacy practice related to dispensing of prescription opioids), 8–9 (lack of knowledge about federal regulation of the opioid industry). The question, then, is whether his experience can serve as a basis for these opinions. "In cases where the proffered expert relies 'solely or primarily on experience, then *the witness must explain how* that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2019 WL 3934597, at *2 (N.D. Ohio Aug. 20, 2019) (emphasis added) (quoting Fed. R. Evid. 702, advisory committee note, 2000 amend.). Dr. Marshalek has not provided any such explanation, and the Court should accordingly exclude his opinions related to pharmacy dispensing of opioids and regulation of the opioid industry.

I. Marshalek's Experience as a Physician and Prescriber of Controlled Substances Does Not Qualify Him to Opine on Pharmacy Practice Related to the Dispensing of Prescription Opioids.

According to Kroger, Dr. Marshalek's opinions as to pharmacies' and pharmacists' dispensing of prescription opioids "are based on his expertise as a medical doctor who treats patients with opioid use disorder [(OUD)] and as a prescriber of controlled substances." Opp'n at 4. But Dr. Marshalek does not explain *how* his experience treating OUD and prescribing controlled substances to patients relates to his conclusions regarding pharmacists' dispensing of prescription opioids. At most, and as Kroger notes in his deposition testimony, Dr. Marshalek explains that pharmacists are "not in a position to question the legitimacy of [opioid] prescriptions," Opp'n Ex. B (Dkt. 4949-2), at 155:13–15, in part because "[t]hey weren't in the doctor's office where [the prescription] was being written" and therefore "don't know if it was just handed to that person by an office staff . . . or if it was a legitimate pain

management practice," *id.* at 156:20–157:3. Dr. Marshalek adds: "I think [pharmacists are] at a distinct disadvantage to question and to kind of call . . . into question" whether a prescription was written for a legitimate medical purpose, and that "I just don't know how they can since they weren't in the office where the patient was being diagnosed and treated and that [prescriber's] recommendation sprang forth." *Id.* at 157:4–11, 157:23–158:2.

Simply put, Dr. Marshalek's opinion is that he knows from his own experience that pharmacists are not in the room with him when he treats patients and writes prescriptions for them. Or, to use Kroger's articulation: "His opinion that the pharmacists' position downstream from the prescriber prevents and *limits* the pharmacists' ability to question the legitimacy of prescription is wholly based on his knowledge, as a medical doctor, that pharmacists are unable to engage in the process of informed consent in patient examination that medical doctors enjoy." Opp'n at 7 (emphasis in original) (citing Marshalek Rep.). The problem is that this opinion is hardly "'helpful to the trier of fact' to better understand the difficulties pharmacists face when dispensing opioids," as Kroger would have it, *id.* (quoting Fed. R. Evid. 702(a)(2))—rather, it is decidedly unhelpful.

To begin with, it hardly requires special expertise to know that pharmacists are not in the room when doctors write prescriptions; this is within the common experience of jurors. Moreover, Dr. Marshalek's "spin" on this commonly known fact is not the product of expertise, and is not helpful, because Dr. Marshalek does not know about "corresponding responsibility," "red flags," or even "due diligence" in the context of dispensing prescription opioids. *See* Pl.'s Mem. at 4–6.[1] Without any

[1] Kroger maintains that Dr. Marshalek's unfamiliarity with "terms of persuasion" such as red flags goes to his credibility and not qualifications, Opp'n at 5, but the concepts that prove so elusive to Dr. Marshalek are not terms of persuasion so much as they are fundamentals in pharmacy practice related to the dispensing of controlled substances. This Court has previously concluded that testimony regarding pharmacy dispensing of opioids requires "expertise in the factors that have fueled the opioid epidemic, such as the circumstances surrounding the supply and availability of opioids, as well as those related to the drug-seeking behaviors of opioid-seeking pharmacy customers (*i.e.*, red flags)." *In re Nat'l Prescription Opiate Litig.*, 2021 WL 4243084, at *7 (permitting majority of testimony by Dr. Lembke as to pharmacy dispensing policies and practices).

understanding of pharmacists' "unique scope of practice," Pl.'s Mem. Ex. B (Dkt. 4885-2) at ECF No. 4, Dr. Marshalek suggests that pharmacists cannot meaningfully evaluate the legitimate medical purpose of opioid prescriptions relative to the prescribers who issue them. Of course, it is self-evident that a prescriber, whether behaving illegally or not, will always have the most insight into the legitimacy of the medical purpose of a prescription that they issue. But Dr. Marshalek's implication that pharmacists do not have their own (federally mandated) tools to combat diversion—tools of which he is seemingly unaware—is not grounded in expertise of any kind; on the contrary, it is grounded in Dr. Marshalek's *ignorance* of the basic regulatory structure and the tools available to pharmacists and pharmacies.

Kroger further attempts to buttress the salience of Dr. Marshalek's medical experience by asserting that, "as a practicing 'clinician with prescriptive authority' and healthcare administrator, [Dr. Marshalek] regularly interacts with pharmacists and pharmacies." *Id.* at 2 (internal citation omitted). Indeed, Dr. Marshalek testified that "pharmacists are on some of the teams that I work on," Pl.'s Mem. Ex. A (Dkt. 4885-1), at 15:4–6, and that "I interface with pharmacists and pharmacies on a regular basis," *id.* at 16:9–11. What Dr. Marshalek does not explain, however, is *how* or *why* his regular interfacing with pharmacists has provided him with expertise as to pharmacists' dispensing of opioids. Kroger seems to argue that this interaction has imbued Dr. Marshalek with knowledge about pharmacists' dispensing practices, seemingly by osmosis, but this is plainly false. *See* Pl.'s Mem. at 4–7. Mere "interaction" with experts in another field is not enough to establish expertise; if it were, countless experts would find themselves experts countless times over. The Court should not permit Dr. Marshalek to opine on pharmacy practice where the basis of his opinions is his interactions with pharmacists with no further demonstrated knowledge about pharmacist dispensing practices for controlled substances.

This Court's orders regarding plaintiff's expert Dr. Anna Lembke, a medical doctor and addiction specialist, in Case Track 3 are instructive. Prior to trial, the Court granted in part pharmacy

defendants' motion to exclude Dr. Lembke's opinions where "[her] expertise does not allow her to opine on any and every Pharmacy policy or procedure." 2021 WL 4243084, at *7. Following trial, the Court denied defendants' motion to exclude her testimony after defendants asserted that her remaining opinions as to their "national policies and procedures" "exceeded the scope of [her] expertise and qualifications." *In re Nat'l Prescription Opiate Litig.*, 589 F. Supp. 3d 790, 829 (N.D. Ohio 2022). The Court found that, through her report and testimony, Dr. Lembke established her "extensive medical knowledge and expertise regarding 'red flags' that signal possible opioid addiction," and that, "[a]t the *Daubert* hearing, Lembke explained the basis for these findings, and her Report provides detailed support for her testimony in this regard." *Id.* at 829–30. As a result, the Court concluded that her testimony regarding pharmacy defendants' policies and procedures concerning controlled substance dispensing "fell squarely within the scope of her extensive medical knowledge and expertise." *Id.* at 830 (footnote omitted). Unlike Dr. Lembke, Dr. Marshalek has provided no such detailed explanation. His report is approximately four pages long, *see* Pl.'s Mem. Ex. B (Dkt. 4885-2), and his conclusory opinions about pharmacy dispensing of opioids amount to a few sentences without any explanation of the expertise that qualifies him to offer them. As already noted, Dr. Marshalek's deposition testimony, too, establishes his lack of knowledge of the most basic aspects of pharmacy practice.

The case law on which Kroger relies also does not support Kroger's position. Dr. Marshalek was not merely "unfamiliar with pertinent statutory definitions" in the pharmacy context, *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at *2 (quoting *Davis Combustion Eng'g, Inc.*, 742 F.2d 916, 919 (6th Cir. 1984));[2] he testified that he is unfamiliar "with the obligations that pharmacies have before dispensing opioids" and could not recall the *key terminology* that governs pharmacies' and

[2] Of note, while the Court quoted this language in the cited order, the Court did not make any findings as to the expert's qualifications because defendants did not challenge them. *See* 2019 WL 3934597, at *6 ("Defendants do not challenge her qualifications. But defendants do ask the Court to exclude Rosenthal's report and testimony for a number of other reasons . . . .")

pharmacists' dispensing of prescription opioids. Pl.'s Mem. at 2 (internal citations omitted). Dr. Marshalek's lack of knowledge is distinguishable from the instances in which the Sixth Circuit has determined that an expert possessed experience that formed an adequate basis for a proffered opinion. *See Surles ex rel. Johnson v. Greyhound lines, Inc.*, 474 F.3d 288, 294 (6th Cir. 2007) (district court did not abuse its discretion in permitting testimony of expert who was "a specialist in threat assessment" even though he "lacked expertise in the *very specialized area* of commercial bus line threat assessment" (emphasis added)); *First Tenn. Bank Nat'l Ass'n v. Barreto*, 268 F.3d 319, 333 (6th Cir. 2001) (district court did not abuse its discretion in permitting testimony of expert with a decades-long career in banking to opine about particular lender-borrower relationship and related banking issues, for any "lack[] [of] familiarity with *some* aspects of banking relationships . . . merely affected the weight and credibility of his testimony" (emphasis added)). Here, Dr. Marshalek does not lack experience in merely a subpart of his general area of expertise; he lacks expertise in an entire field to which his opinions pertain. The Court should exclude his pharmacy dispensing opinions as beyond the scope of his expertise.

II. Marshalek's Registration with the DEA and Work as a DEA Consultant Do Not Qualify Him to Opine on Federal Regulation of the Opioid Industry.

Kroger similarly seeks to bolster Dr. Marshalek's experience to opine about federal regulation of the opioid industry by insisting that, "like pharmacists, and pharmacies, Dr. Marshalek is registered with the DEA to dispense controlled substances, including prescription opioids." Opp'n at 2 (citing 21 U.S.C. § 822(a)(2)); *see also id.* at 8–9 (noting that Dr. Marshalek is "a controlled substance prescriber registered with the DEA"). It is unclear how Dr. Marshalek's registration with the DEA alone constitutes expertise or experience sufficient to support his opinions as to federal agencies' regulation of the opioid industry. Kroger does not, and indeed cannot, point to any relevant deposition testimony or excerpts of Dr. Marshalek's Report that elucidate this connection.

Kroger also reiterates that Dr. Marshalek is an "experienced DEA consultant." *Id.* at 1, 4, 8, 9.

But, aside from these tiresome repetitions, Kroger does not explain *how* or *why* this experience consulting for the DEA in its investigation and prosecution of pill mill prescribers translates to knowledge about DEA oversight of the opioid industry, let alone the industry's regulation by other federal agencies. The closest Kroger comes to articulating a link—"from his experience as a DEA consultant in connection with 'pill mills,' he believes that pill mill prescribers and community pharmacies connected with pill mills also contributed to the overdose epidemic," Opp'n at 9 (internal citation omitted)—is hardly a sufficient explanation. Regardless, and more importantly, despite his asserted "experience" as a DEA consultant, Dr. Marshalek could not describe any specifics about DEA quotas for manufacturing opioids or other regulatory processes that the DEA or FDA may take with respect to controlled substances and in particular, opioids. *See* Pl.'s Mem. at 8–9. Kroger instead points to the fact that Dr. Marshalek's Report cited exactly three sources on these topics, *see* Opp'n at 10 nn.4–7, but, at his deposition, Dr. Marshalek was unable to elaborate on them to any extent, Pl.'s Mem. at 8 (internal citations omitted). Again, Dr. Marshalek fails to explain how his experience as a DEA consultant in the context of prosecuting pill mill prescribers leads to his conclusions about, for example, DEA regulations pertaining to opioid manufacturers or the nature of FDA's REMs programs. *See In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at *2.

Kroger also maintains that Dr. Marshalek's opinion as to the role of federal regulators "is properly supported by his citation to the Stanford-*Lancet* Report." Opp'n at 9 (internal citation omitted). As one example, Kroger identifies an excerpt from the Stanford-*Lancet* Report that notes: "[H]ad the [FDA] conducted marketing studies of the many approved opioid medications been promptly done, the risks of addiction would have come to light more quickly . . . ." *Id.* at 10 (alterations in original). But Dr. Marshalek does not rely on the Stanford-*Lancet* Report for this proposition; rather, Dr. Marshalek cites it for the proposition that: "Far upstream from the busy prescriber, pharmacist, and community pharmacy sat those with power and ability to limit the overall amount of prescriptions that ultimately contributed to the epidemic of overdose deaths." Pl.'s Mem. at 9 (quoting Marshalek Rep.).

The role that marketing studies conducted by the FDA might have played in shedding light on the risks of addiction of opioid medications is not synonymous with the vague pronouncement that "those with power and ability"—presumably, federal agencies writ large—were able "to limit the overall amount of prescriptions" without further detail. Moreover, as is true with the fact that pharmacists are not in the room when doctors prescribe, the assertion that pharmacists sit downstream from manufacturers and regulators is also not the product of expertise, but rather, again, is a commonly-known fact. Dr. Marshalek's "knowledge" of this common fact does not give him the requisite expertise to assess the causes of the opioid crisis.

More broadly, the problem with Kroger's defense of Dr. Marshalek's reliance on the Stanford-*Lancet* Report is the implication that Dr. Marshalek could simply restate its conclusions. This is not acceptable expert testimony. *See, e.g.*, *Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 844 (N.D. Ohio 2011) ("An expert must make some findings and not merely regurgitate another expert's opinion." (quotation marks and citation omitted)). Contrary to Kroger's argument, Plaintiff does not "question[] the accuracy of Dr. Marshalek's conclusion" as gleaned from the Stanford-*Lancet* Report; Plaintiff maintains that Dr. Marshalek may not simply report someone else's conclusion where he is not qualified to offer the opinion independent of the publication by virtue of any demonstrated knowledge or experience.

Dr. Marshalek's testimony in areas so far beyond his knowledge and experience are particularly dangerous because he possesses an impressive set of credentials and many years of experience in healthcare and medicine that can be misunderstood by the jury to support his broader comments. This is precisely why experts' testimony is limited to particular areas, for "where one person sees speculation, we acknowledge, another may see knowledge, which is why the district court enjoys broad discretion over where to draw the line." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 672 (6th Cir. 2010). *See also, e.g.*, *Rheinfrank v. Abbott Labs, Inc.*, 680 F. App'x 369, 380 (6th Cir. 2017); *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014). Dr. Marshalek has not established that he has

knowledge or experience sufficient to offer expert opinions about (1) pharmacy dispensing of opioid prescriptions, and (2) federal agencies' regulation of the opioid industry. The Court should grant Plaintiff's motion to exclude Dr. Marshalek's opinions in these two categories.

March 23, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/Peter H. Weinberger
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